



General

Guideline Title

ACR Appropriateness Criteria® asymptomatic patient at risk for coronary artery disease.

Bibliographic Source(s)

Earls JP, Woodard PK, Abbara S, Akers SR, Araoz PA, Cummings K, Cury RC, Dorbala S, Hoffmann U, Hsu JY, Jacobs JE, Min JK, Expert Panel on Cardiac Imaging. ACR Appropriateness Criteria® asymptomatic patient at risk for coronary artery disease. [online publication]. Reston (VA): American College of Radiology (ACR); 2013. 12 p. [72 references]

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

ACR Appropriateness Criteria®

Clinical Condition: Asymptomatic Patient at Risk for Coronary Artery Disease

Variant 1: Low risk.

Radiologic Procedure	Rating	Comments	RRL*
CT coronary calcium	3	In patients with strong family history, this study may be of value.	<input type="text"/> <input type="text"/> <input type="text"/>
Fluoroscopy heart	2		<input type="text"/> <input type="text"/>
US echocardiography transthoracic resting	2		O
X-ray chest	1		<input type="text"/>
Rating Scale: 1, 2, 3 Usually not appropriate; 4, 5, 6 May be appropriate; 7, 8, 9 Usually appropriate			*Relative Radiation

Radiologic Procedure	Rating	Comments	RRL*
CTA coronary arteries with contrast low dose	1		
MRI heart with stress without and with contrast	1		O
MRI heart with stress without contrast	1		O
MRI heart function and morphology without and with contrast	1		O
MRI heart function and morphology without contrast	1		O
MRA coronary arteries without contrast	1		O
MRA coronary arteries without and with contrast	1		O
SPECT MPI rest and stress	1		
US echocardiography transthoracic stress	1		O
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 2: Intermediate risk.

Radiologic Procedure	Rating	Comments	RRL*
CT coronary calcium	8		
CTA coronary arteries with contrast	3		
CTA coronary arteries with contrast low dose	3		
US echocardiography transthoracic stress	3		O
X-ray chest	2		
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation

Radiologic Procedure	Rating	Comments	RRL*
MRI heart with stress without and with contrast	2		O
MRI heart with stress without contrast	2		O
MRI heart function and morphology without and with contrast	2		O
MRI heart function and morphology without contrast	2		O
MRA coronary arteries without contrast	2		O
MRA coronary arteries without and with contrast	2		O
SPECT MPI rest and stress	2		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
US echocardiography transthoracic resting	2		O
<u>Rating Scale:</u> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 3: High risk.

Radiologic Procedure	Rating	Comments	RRL*
MRI heart with stress without and with contrast	5	See statement regarding contrast in text below under "Anticipated Exceptions."	O
US echocardiography transthoracic stress	5		O
SPECT MPI rest and stress	5		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
CTA coronary arteries with contrast low dose	5		<input type="text"/> <input type="text"/> <input type="text"/>
CTA coronary arteries with contrast	4		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
MRI heart with stress without contrast	4		O
<u>Rating Scale:</u> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Imaging Modality	Rating	Comments	RRL*
ECG			
Resting transthoracic			
resting			
MRI heart function and morphology without and with contrast	3		O
MRI heart function and morphology without contrast	3		O
MRA coronary arteries without and with contrast	3		O
MRA coronary arteries without contrast	2		O
X-ray chest	2		<input type="text"/>
Fluoroscopy heart	2		<input type="text"/> <input type="text"/>
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Summary of Literature Review

Introduction/Background

In the United States, atherosclerotic cardiovascular disease (CVD) is the leading cause of death for both men and women. Although improvements in awareness, knowledge, and medications have led to a decrease in death rates, the burden of disease remains very high. Because atherosclerotic coronary artery disease (CAD) has a long and asymptomatic latent period, it is believed that early targeted preventive measures would be a great benefit to reducing mortality and morbidity. To identify patients who might benefit from early intervention, it is essential to accurately classify individuals who are asymptomatic but at elevated risk.

CVD prevention has traditionally been based on the assessment of a patient's conventional risk-factor profile, a combined evaluation based on genetic, social, physiological, and environmental factors. Risk assessment for CAD is intended to aid in determining the appropriate lifestyle changes and pharmacological interventions to reduce a patient's risk of cardiac death. A global risk score, such as Framingham, Reynolds, Systematic Coronary Risk Evaluation, or Prospective Cardiovascular Munster, is used to categorize patient risk as low, intermediate, or high. However, these risk factors are strong population-based markers but poor individual discriminators of CAD disease, and many individuals with 1 or more risk factors do not experience a cardiac event.

There is a growing discordance between the recognized ability of current risk estimation tools to predict outcomes versus that of actual measured outcomes. Recent imaging advances have made it possible to detect subclinical coronary atherosclerosis. The coronary artery calcium score (CACS) is a marker of vascular injury that correlates closely with the overall atherosclerotic burden. Individual data derived from this and other imaging tests provide useful prognostic information for patient management and can complement current risk prediction models.

Non-imaging-based diagnostics, such as exercise treadmill testing, are also used for assessing asymptomatic patients who have an elevated risk for CVD. The added value of imaging-based tests has been previously established; therefore, a discussion of the use of non-imaging-based tests is beyond the scope of this document. The purpose is to discuss the use of diagnostic imaging tests in asymptomatic patients who are at elevated risk for future cardiovascular events. The assessment goal for these patients is to further refine targeted preventative efforts based on patient risk. Diagnostic imaging tests are used only in asymptomatic patients at elevated cardiovascular risk. (Imaging use in patients who have a known diagnosis of CAD, cardiac symptoms, history of a coronary event, or prior intervention can be found in other ACR Appropriateness Criteria®.)

The following imaging modalities are available for evaluating asymptomatic patients at elevated risk for CAD: chest radiography, chest fluoroscopy, multidetector computed tomography (CT) (MDCT), ultrasound (US), magnetic resonance imaging (MRI), cardiac perfusion scintigraphy, echocardiography, and positron emission tomography (PET).

Chest Radiography

A chest radiograph is commonly used in asymptomatic individuals as part of a routine physical examination or presurgical testing. A routine chest radiograph can detect unsuspected abnormalities of the lungs and thorax, assess for cardiomegaly, detect coronary calcium, or serve as a baseline for future measurement. Radiographs of the chest can depict the presence of coronary artery calcifications, which are indicative of CAD. Radiographic analyses of living and autopsied patients have demonstrated that coronary calcification is easily detected, occurs frequently, increases with age, and can indicate severe underlying lesions. There is also an association between aortic arch calcification depicted on chest radiography and CAD.

Chest Fluoroscopy

Fluoroscopic visualization of coronary calcification is a noninvasive method used mainly in the past as a screening technique for CAD. The prevalence of CAD in patients with fluoroscopically detected coronary artery calcifications is significantly greater than in those without calcifications. When compared with coronary angiography, chest fluoroscopy of an asymptomatic military flight crew demonstrated an overall sensitivity and specificity of 66.3% and 77.6%, respectively, for detecting significant CAD. Patients who have calcification detected by chest fluoroscopy also have a significantly poorer survival.

Computed Tomography: Coronary Artery Calcium Scoring

CACS, performed on either an electron-beam CT or MDCT is a proven marker for the presence of coronary atherosclerosis and risk of future cardiovascular events. CACS is useful in risk stratification and reclassification, as a strong association has been found between the calcium score and future mortality and/or adverse cardiac events. Many trials have found evidence of the prognostic use of CACS. One study followed 10,377 asymptomatic patients for 5 ± 3.5 years and found CACS to be an independent predictor of death that increased proportionally relative to baseline, with an adjusted relative risk of 1.6, 1.7, 2.5, and 4 for CACS 11–100, 101–400, 401–1,000, and >1,000, respectively.

CACS provides incremental prognostic information beyond traditional risk factor evaluation. In the St. Francis Heart Study, a CACS >100 predicted CAD events independently of standard risk factors. One research group found that any measurable coronary calcium was independently related to hard (death and myocardial infarction [MI]) and soft (revascularization procedure) events in men and women; this finding provided incremental prognostic information over conventional risk factors. Another study also demonstrated incremental risk beyond age, gender, ethnicity, and cardiac risk factors in evaluating data from 25,253 asymptomatic patients who had a 10-year adjusted survival rate of 99.4% for a CACS of 0 and 87.8% for a score >1,000.

CACS can be used to stratify and reclassify patient risk more accurately than traditional methods. In 2 recent large-population-based studies, CACS demonstrated a high reclassification rate in the intermediate-risk cohort. This finding further supports the benefit of imaging of subclinical coronary atherosclerosis when compared with traditional risk categorization. These 2 independent observational and prospective studies showed a high net reclassification index (NRI) based on a CACS approach. In the Multi-Ethnic Study of Atherosclerosis, researchers used CACS, in conjunction with their conventional Framingham Risk Score, to evaluate 5,878 asymptomatic men and women. In that study, the NRI was 25%, an additional 23% of subjects with events were reclassified to the high-risk category, and 13% of subjects without events were reclassified to the low-risk category. The Heinz Nixdorf Recall Study, a large population-based study with nearly 5,000 participants and a 5-year follow-up, demonstrated a NRI of 24% and 19% as high- and low-risk groups, respectively.

Several guidelines on imaging of asymptomatic CAD included recommendations for using CACS. The *2010 Appropriate Use Criteria for Cardiac Computed Tomography* found that CACS use was appropriate in asymptomatic, intermediate-risk patients and in low-risk patients who had a family history of premature CAD. Other guidelines concluded there was sufficient evidence to consider recommending CACS, and one guideline recommended its use. These guidelines recommended CACS exclusively in patients at intermediate risk for CAD. For patients at low and high risk for CAD, the guidelines were unanimous in not advocating CT calcium scoring.

Computed Tomography: Coronary Angiography

Coronary CT angiography (CCTA) noninvasively assesses patency of the coronary lumen, the arterial wall, calcified and noncalcified plaques, and ventricular function. In addition to many single-center studies, 3 multicenter trials evaluated the diagnostic use of 64-slice CCTA and reported sensitivities for detecting a 50% stenosis from 85% to 99%, with negative predictive values from 83% to 99%. It is not known, however, whether CCTA can be used as a prognostic tool, independent of CACS and clinical risk models, to stratify asymptomatic patients and predict future cardiac events.

Several studies examined CAD in asymptomatic patients and reported a relatively high prevalence of occult atherosclerosis; this discovery could have a significant impact on therapeutic decision-making and management. One relatively large study of 1,000 asymptomatic patients reported using CCTA to evaluate the prevalence of occult CAD and its ability to predict future adverse coronary events. Among asymptomatic patients, one study found atherosclerotic plaques in 22%, stenoses of $\geq 50\%$ in 5%, and stenosis of $\geq 75\%$ in 2%. Of those who had significant stenosis, 25% were initially classified as low-risk according to National Cholesterol Education Program criteria, and 58% had CACS <100. At midterm

follow-up (17 ± 2 months) all coronary events occurred in individuals for whom CCTA had depicted CAD. In another study using CCTA, two-thirds of asymptomatic diabetics were found to have occult CAD, including 26% with obstructive disease. Another group of authors retrospectively assessed the value of CCTA in predicting cardiac events in 451 asymptomatic patients, with a median follow-up of 27.5 months. In 48% of patients, CCTA could be used to reclassify the clinically assessed cardiovascular risk from intermediate- or high- to low-risk.

In patients who had suspected but undocumented CAD, a group of researchers evaluated the incremental prognostic value of CCTA against both a traditional clinical-risk model and calcium scoring. While CACS again had significant incremental prognostic value compared with a baseline clinical-risk model, CCTA provided an additional incremental prognostic value, compared with a baseline clinical-risk model plus CACS. The presence of noncalcified or mixed plaques, regardless of lesion severity, was found to be the strongest predictor of events ($P < .0001$) as a potential marker of plaque vulnerability.

Results from both CACS and CCTA studies have demonstrated that patients who have occult CAD could be misclassified when conventional risk-stratification algorithms are used. In symptomatic patients, CT can independently predict future events, and data suggest it can yield improved risk stratification beyond traditional scoring methods. In asymptomatic patients, CACS can also be used to stratify and reclassify patient risk more accurately than traditional methods. Using CCTA in asymptomatic patients remains controversial, primarily because of the higher radiation dose, added cost, and use of nephrotoxic contrast, but it has the potential to identify useful data beyond what is derived from CACS. As detailed in the *2010 ACCF/AHA Guideline for Assessment of Cardiovascular Risk in Asymptomatic Adults: Executive Summary*, CCTA is not recommended for cardiovascular risk assessment in asymptomatic adults.

Recent advances in cardiac CT imaging technology allow for further reduction of the radiation dose from CCTA; available new dose-reducing techniques include prospective triggering, adaptive statistical iterative reconstruction, and high-pitch spiral acquisition. These new lower-dose techniques are the appropriate choice in properly selected patients who have a low heart rate (<65 beats per minute) and are in sinus rhythm.

Magnetic Resonance Imaging

Cardiac MRI is an accurate and reliable means for evaluating cardiac anatomy and ventricular function. Recent progress has shown it to be an excellent method for evaluating myocardial ischemia and infarction. Stress first-pass contrast-enhanced myocardial perfusion MRI detects subendocardial ischemia with high diagnostic accuracy in patients with significant CAD. Wall motion abnormalities identified during dobutamine stress MRI accurately identify patients at increased risk for cardiac death and MI; patients with normal findings have very low risk for future cardiac events.

Assessment of myocardial viability is important in predicting functional recovery after revascularization and in risk stratification of patients who have CAD. Although coronary MRA does not expose patients to radiation, like CACS or CCTA, noninvasive MRI of the coronary artery is technically demanding due to the small size and tortuous course of the coronary arteries and the complex motion caused by cardiac contraction and respiration.

In asymptomatic patients, MRI of the coronary wall may enhance risk stratification by quantifying the subclinical coronary atherosclerotic plaque burden. In a subset of asymptomatic patients in the Multi-Ethnic Study of Atherosclerosis, coronary arterial remodeling was evaluated using coronary wall MRI as a marker of subclinical atherosclerosis. MRI detected positive arterial remodeling in asymptomatic men and women who had subclinical atherosclerosis. Recently, the presence of unrecognized MI in asymptomatic patients, as detected by contrast-enhanced MR, was associated with increased mortality risk and more strongly associated with mortality than electrocardiogram; the presence of unrecognized MI improved risk stratification for mortality over recognized MI. Currently, no consensus guideline recommends the use of MRI for risk stratification in asymptomatic patients.

Cardiac Perfusion Scintigraphy

Myocardial perfusion scintigraphy (MPS) can detect silent myocardial ischemia but is limited in its ability to detect early or subclinical atherosclerosis. Patients undergoing MPS who do not show inducible ischemia have a very low ($<1\%$ per year) cardiac event rate during the following 2 to 3 years. The prevalence of silent myocardial ischemia in asymptomatic populations varies significantly. In nondiabetic patients, evidence of silent ischemia increases from 2% in the fifth and sixth decades to 15% in the ninth decade.

A positive MPS is an independent predictor of future coronary events, and it is independent of conventional risk factors. Use of MPS in asymptomatic individuals who have intermediate risk is effective for CAD detection and risk stratification. In asymptomatic patients at moderate risk for CAD, one report showed that the annual mortality was 4.0% in patients with a positive MPS versus 1.6% in those who had normal scans. Another study evaluated 3,664 consecutive asymptomatic patients with no prior diagnosis of CAD who were undergoing MPS and followed them for 1 year or more. They reported that patients with $\geq 7.5\%$ myocardium ischemia had a significantly greater risk (3.1% major event rate per year) than those with less ischemia (0.4% major event rate).

Asymptomatic patients who have type 2 diabetes have a higher cardiac risk than nondiabetic patients. The average annual hard event rate (cardiac death or MI) in diabetic patients with a normal MPS was 0.85%, as opposed to 5.9% in those with a moderately to severely abnormal MPS. However, for any degree of perfusion abnormality, the risk in diabetic patients is higher compared with nondiabetic patients. Recently, one group reported a prevalence of 21% abnormal MPS using gated ^{99m}Tc -sestamibi in the Detection of Silent Myocardial Ischemia in Asymptomatic Diabetics study. The presence of moderate to large ischemic defects was associated with a significantly higher event rate (2.4% per year) compared with patients who had normal perfusion or small perfusion abnormalities (0.4% per year).

As detailed in the *2010 ACCF/AHA Guideline for Assessment of Cardiovascular Risk in Asymptomatic Adults: Executive Summary*, stress myocardial perfusion imaging (MPI) is indicated for risk assessment in asymptomatic adults who have diabetes or asymptomatic adults who have a strong family history of congenital heart disease; it is also indicated when previous risk-assessment testing has suggested a high risk of CHD, such as a CACS >400. Stress MPI is not indicated for cardiovascular risk assessment in low- or intermediate-risk asymptomatic adults.

Echocardiography

Stress echocardiography can be used for screening high-risk asymptomatic patients. It is most commonly used before major noncardiac surgery. A number of studies have demonstrated that the yearly event rate following a normal exercise or dobutamine stress echocardiography (DSE) is only 0.4% to 0.9%, a value similar to that following a normal MPS. Prognostic data from stress echocardiography can be used to risk-stratify patients. Following a normal stress echocardiogram, the cardiac event-free survival rates at 1, 2, and 3 years are 99.2%, 97.8%, and 97.4%, respectively. Subgroups with an intermediate or high pretest probability of CAD also had low cardiac event rates.

One study showed that the rate of cardiac death or MI in patients who had a new abnormal stress echocardiogram increased 3.6- and 2.5-fold, respectively. They also reported that DSE can assess the risk for future cardiac events by distinguishing subgroups of patient with high (>30% in 5 years), median (12% in 5 years), and low (8% in 5 years) risk. Importantly, patients with normal DSE have a good prognosis. In symptomatic patients who have new onset of chest pain and no previously known CAD, stress echocardiography is an independent and incremental predictor of hard cardiac events beyond that provided by electrocardiogram and clinical data alone.

Despite these results, stress echocardiography is not indicated for cardiovascular risk assessment in low- or intermediate-risk asymptomatic adults.

Summary

- Recent imaging advances have made it possible to detect subclinical coronary atherosclerosis. A number of imaging modalities may be used for evaluating asymptomatic patients at elevated risk for future cardiovascular events.
- The goal of assessment in asymptomatic patients is to refine targeted preventative efforts based on patient risk.
- In low-risk patients, all modalities were considered "usually not appropriate", but the panel did comment that CACS may be useful in low-risk patients who have a strong family history of coronary risk.
- In intermediate-risk patients, CACS was determined to be "usually appropriate", as it can be used to stratify and reclassify patient risk more accurately than traditional methods.
- In high-risk patients, it was determined that CCTA and stress-and-rest studies using MRI, single-photon emission CT, MPI, and ultrasound "may be appropriate."

Anticipated Exceptions

Nephrogenic systemic fibrosis (NSF) is a disorder with a scleroderma-like presentation and a spectrum of manifestations that can range from limited clinical sequelae to fatality. It appears to be related to both underlying severe renal dysfunction and the administration of gadolinium-based contrast agents. It has occurred primarily in patients on dialysis, rarely in patients with very limited glomerular filtration rate (GFR) (i.e., <30 mL/min/1.73 m²), and almost never in other patients. There is growing literature regarding NSF. Although some controversy and lack of clarity remain, there is a consensus that it is advisable to avoid all gadolinium-based contrast agents in dialysis-dependent patients unless the possible benefits clearly outweigh the risk, and to limit the type and amount in patients with estimated GFR rates <30 mL/min/1.73 m². For more information, see the American College of Radiology (ACR) Manual on Contrast Media (see the "Availability of Companion Documents" field).

Abbreviations

- CT, computed tomography
- CTA, computed tomography angiography
- MRA, magnetic resonance angiography
- MRI, magnetic resonance imaging
- SPECT MPI, single photon emission computed tomography myocardial perfusion imaging
- US, ultrasound

Relative Radiation Level Designations

Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range
O	0 mSv	0 mSv
<input type="text"/>	<0.1 mSv	<0.03 mSv
<input type="text"/> <input type="text"/>	0.1-1 mSv	0.03-0.3 mSv
<input type="text"/> <input type="text"/> <input type="text"/>	1-10 mSv	0.3-3 mSv
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	10-30 mSv	3-10 mSv
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	30-100 mSv	10-30 mSv
*RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (e.g., region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as "Varies".		

Clinical Algorithm(s)

Algorithms were not developed from criteria guidelines.

Scope

Disease/Condition(s)

Coronary artery disease

Guideline Category

Diagnosis

Evaluation

Clinical Specialty

Cardiology

Emergency Medicine

Family Practice

Internal Medicine

Radiology

Intended Users

Health Plans

Hospitals

Managed Care Organizations

Physicians

Utilization Management

Guideline Objective(s)

To evaluate the appropriateness of initial radiologic examinations for asymptomatic patients at risk for coronary artery disease

Target Population

Patients at risk for coronary artery disease

Interventions and Practices Considered

1. Computed tomography (CT) coronary calcium
2. Fluoroscopy heart
3. Ultrasound (US) transthoracic echocardiography
 - Resting
 - Stress
4. X-ray chest
5. Computed tomography angiography (CTA) coronary arteries
 - With contrast
 - With contrast low dose
6. Magnetic resonance imaging (MRI) heart
 - With stress without and with contrast
 - Function and morphology without and with contrast
 - Function and morphology without contrast
7. Magnetic resonance angiography (MRA) coronary arteries
 - Without contrast
 - Without and with contrast
8. Single proton emission computed tomography (SPECT) myocardial perfusion imaging (MPI) rest and stress

Major Outcomes Considered

- Mortality
- Utility of radiologic examinations in differential diagnosis and screening

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search Procedure

Staff will search in PubMed only for peer reviewed medical literature for routine searches. Any article or guideline may be used by the author in the narrative but those materials may have been identified outside of the routine literature search process.

The Medline literature search is based on keywords provided by the topic author. The two general classes of keywords are those related to the condition (e.g., ankle pain, fever) and those that describe the diagnostic or therapeutic intervention of interest (e.g., mammography, MRI).

The search terms and parameters are manipulated to produce the most relevant, current evidence to address the American College of Radiology Appropriateness Criteria (ACR AC) topic being reviewed or developed. Combining the clinical conditions and diagnostic modalities or therapeutic procedures narrows the search to be relevant to the topic. Exploding the term "diagnostic imaging" captures relevant results for diagnostic topics.

The following criteria/limits are used in the searches.

1. Articles that have abstracts available and are concerned with humans.
2. Restrict the search to the year prior to the last topic update or in some cases the author of the topic may specify which year range to use in the search. For new topics, the year range is restricted to the last 10 years unless the topic author provides other instructions.
3. May restrict the search to Adults only or Pediatrics only.
4. Articles consisting of only summaries or case reports are often excluded from final results.

The search strategy may be revised to improve the output as needed.

Number of Source Documents

The total number of source documents identified as the result of the literature search is not known.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Strength of Evidence Key

Category 1 - The conclusions of the study are valid and strongly supported by study design, analysis and results.

Category 2 - The conclusions of the study are likely valid, but study design does not permit certainty.

Category 3 - The conclusions of the study may be valid but the evidence supporting the conclusions is inconclusive or equivocal.

Category 4 - The conclusions of the study may not be valid because the evidence may not be reliable given the study design or analysis.

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The topic author drafts or revises the narrative text summarizing the evidence found in the literature. American College of Radiology (ACR) staff draft an evidence table based on the analysis of the selected literature. These tables rate the strength of the evidence (study quality) for each article included in the narrative text.

The expert panel reviews the narrative text, evidence table, and the supporting literature for each of the topic-variant combinations and assigns an appropriateness rating for each procedure listed in the table. Each individual panel member assigns a rating based on his/her interpretation of the available evidence.

More information about the evidence table development process can be found in the ACR Appropriateness Criteria® Evidence Table Development document (see the "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

Rating Appropriateness

The appropriateness ratings for each of the procedures included in the Appropriateness Criteria topics are determined using a modified Delphi methodology. A series of surveys are conducted to elicit each panelist's expert interpretation of the evidence, based on the available data, regarding the appropriateness of an imaging or therapeutic procedure for a specific clinical scenario. American College of Radiology (ACR) staff distribute surveys to the panelists along with the evidence table and narrative. Each panelist interprets the available evidence and rates each procedure. The surveys are completed by panelists without consulting other panelists. The appropriateness rating scale is an ordinal scale that uses integers from 1 to 9 grouped into three categories: 1, 2, or 3 are in the category "usually not appropriate"; 4, 5, or 6 are in the category "may be appropriate"; and 7, 8, or 9 are in the category "usually appropriate." Each panel member assigns one rating for each procedure for a clinical scenario. The ratings assigned by each panel member are presented in a table displaying the frequency distribution of the ratings without identifying which members provided any particular rating.

If consensus is reached, the median rating is assigned as the panel's final recommendation/rating. Consensus is defined as eighty percent (80%) agreement within a rating category. A maximum of three rounds may be conducted to reach consensus. Consensus among the panel members must be achieved to determine the final rating for each procedure.

If consensus is not reached, the panel is convened by conference call. The strengths and weaknesses of each imaging procedure that has not reached consensus are discussed and a final rating is proposed. If the panelists on the call agree, the rating is proposed as the panel's consensus. The document is circulated to all the panelists to make the final determination. If consensus cannot be reached on the call or when the document is circulated, "No consensus" appears in the rating column and the reasons for this decision are added to the comment sections.

This modified Delphi method enables each panelist to express individual interpretations of the evidence and his or her expert opinion without excessive influence from fellow panelists in a simple, standardized and economical process. A more detailed explanation of the complete process can be found in additional methodology documents found on the [ACR Web site](#) (see also the "Availability of Companion Documents" field).

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The recommendations are based on analysis of the current literature and expert panel consensus.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Selection of appropriate radiologic imaging procedures for asymptomatic patients at risk for coronary artery disease

Potential Harms

Gadolinium-based Contrast Agents

Nephrogenic systemic fibrosis (NSF) is a disorder with a scleroderma-like presentation and a spectrum of manifestations that can range from limited clinical sequelae to fatality. It appears to be related to both underlying severe renal dysfunction and the administration of gadolinium-based contrast agents. It has occurred primarily in patients on dialysis, rarely in patients with very limited glomerular filtration rate (GFR) (i.e., <30 mL/min/1.73 m²), and almost never in other patients. Although some controversy and lack of clarity remain, there is a consensus that it is advisable to avoid all gadolinium-based contrast agents in dialysis-dependent patients unless the possible benefits clearly outweigh the risk, and to limit the type and amount in patients with estimated GFR rates <30 mL/min/1.73 m². For more information, please see the American College of Radiology (ACR) Manual on Contrast Media (see the "Availability of Companion Documents" field).

Relative Radiation Level (RRL)

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, both because of organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared to those specified for adults. Additional information regarding radiation dose assessment for imaging examinations can be found in the ACR Appropriateness Criteria® Radiation Dose Assessment Introduction document (see the "Availability of Companion Documents" field).

Qualifying Statements

Qualifying Statements

The American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Earls JP, Woodard PK, Abbara S, Akers SR, Araoz PA, Cummings K, Cury RC, Dorbala S, Hoffmann U, Hsu JY, Jacobs JE, Min JK, Expert Panel on Cardiac Imaging. ACR Appropriateness Criteria® asymptomatic patient at risk for coronary artery disease. [online publication]. Reston (VA): American College of Radiology (ACR); 2013. 12 p. [72 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2013

Guideline Developer(s)

American College of Radiology - Medical Specialty Society

Source(s) of Funding

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

Guideline Committee

Committee on Appropriateness Criteria, Expert Panel on Cardiac Imaging

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Financial Disclosures/Conflicts of Interest

Not stated

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the [American College of Radiology \(ACR\) Web site](#) .

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

Availability of Companion Documents

The following are available:

- ACR Appropriateness Criteria®. Overview. Reston (VA): American College of Radiology; 2013 Nov. 3 p. Electronic copies: Available in Portable Document Format (PDF) from the [American College of Radiology \(ACR\) Web site](#) .
- ACR Appropriateness Criteria®. Literature search process. Reston (VA): American College of Radiology; 2013 Apr. 1 p. Electronic copies: Available in PDF from the [ACR Web site](#) .
- ACR Appropriateness Criteria®. Evidence table development – diagnostic studies. Reston (VA): American College of Radiology; 2013 Nov. 3 p. Electronic copies: Available in PDF from the [ACR Web site](#) .
- ACR Appropriateness Criteria®. Radiation dose assessment introduction. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in PDF from the [ACR Web site](#) .
- ACR Appropriateness Criteria®. Manual on contrast media. Reston (VA): American College of Radiology; 90 p. Electronic copies: Available in PDF from the [ACR Web site](#) .
- ACR Appropriateness Criteria®. Procedure information. Reston (VA): American College of Radiology; 1 p. Electronic copies: Available in PDF from the [ACR Web site](#) .
- ACR Appropriateness Criteria® asymptomatic patient at risk for coronary artery disease. Evidence table. Reston (VA): American College of Radiology; 2013. 28 p. Electronic copies: Available from the [ACR Web site](#) .

Patient Resources

None available

NGC Status

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